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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,929	04/16/2004	Alexander Lai	57657/04-265	1334

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EXAMINER

SALVOZA, M FRANCO G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/826,929	LAI, ALEXANDER	
	Examiner	Art Unit	
	M. Franco Salvoza	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 and 12-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 7, 2006 has been entered.

Claims 1-4, 6, 12 and 14 have been amended.

Claims 1-10, 12-19 are pending in the application.

### ***Claim Objections***

#### **WITHDRAWN**

The amendment of claim 1 was objected to for allegedly introducing new matter with the amendment to “consisting essentially of.”

Applicant has amended the claim and submits the objection is moot.

Applicant's arguments are considered and found unpersuasive. The objection is withdrawn.

### ***Claim Rejections - 35 USC § 112***

#### **WITHDRAWN**

Claims 1-10, 12-19 were rejected under 35 U.S.C. 112, second paragraph as being indefinite.

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Applicant submits that after amending claim 1 to remove the phrase “consisting essentially of,” the rejection is moot.

Applicant’s arguments are considered and found persuasive. The rejection is withdrawn.

Claims 1-10, 12-19 were rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. (See page 3 of the Final rejection.)

Applicant did not respond to the rejection. However, in light of the amendment the rejection is withdrawn.

### **NEW**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 12-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 1 recites a vaccine for equine influenza virus comprising an effective immunizing amount of an isolated DNA, the isolated DNA comprising sequences that encode an HA1 protein from which HA2 is absent, the sequence being from a strain of equine-2 influenza virus.

It is unclear based on the recitation of the claim whether the HA1 protein is full length or a fragment, since it recites “an HA1 protein.” The claim reads on fragments of the HA1 protein as well.

***Claim Rejections - 35 USC § 102***

**WITHDRAWN**

Claims 1-2, 6-7, 9-10 and 13 were rejected under 35 U.S.C. 102(b) as being anticipated by either Olsen et al. or Lunn et al.

Applicant submits that full-length HA is not required to elicit a protective immune response, and the use of the full-length protein is not optimal. Further, claim 1 has been amended to recite that the form of HA utilized in the invention is HA1 from which HA2 is absent. Thus, Olsen et al. and Lunn et al. teach only the use of full-length HA.

Applicant's arguments are considered and found persuasive. The rejections are withdrawn.

***Claim Rejections - 35 USC § 103***

**WITHDRAWN**

Claims 3-5, 8, 12 and 14-19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al. and Lunn et al. in combination with various secondary references.

Applicant submits that because of the amendment reciting HA1 from which HA2 is absent the invention cannot be deemed obvious in view of any combination of Olsen et al. and Lunn et al. with any other references.

Applicant's arguments are considered and found unpersuasive as to claims 5, 8-12, 14-19. The rejections are withdrawn.

**NEW**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 3, 4, 6, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al. in view of Lai et al. (2001).

Amended claim 1 recites a vaccine for equine influenza virus, comprising: an effective immunizing amount of an isolated DNA, the isolated DNA comprising sequences that encode an HA1 protein from which HA2 is absent, the sequences being from a strain of equine-2 influenza virus; and a pharmacologically acceptable carrier or diluent.

See the teachings of Olsen et al. as recited in the first Office Action on the merits.

Olsen et al. does not teach the sequence that encodes an HA1 protein from which HA2 is absent.

See the teachings of Lai et al. as recited in the first Office Action on the merits.

The specification lists HA1 as “comprising SEQ ID NO:1” (p. 8), meaning that HA1 includes at a minimum SEQ ID NO:1, but may include more.

Lai et al. teaches L39914 a portion or fragment of SEQ ID NO:1 that is 98.8% homologous to SEQ ID NO: 1 (see result 5 of .rge). Thus since the claim reads on an HA1 protein or a fragment of HA1, Lai et al. teaches a fragment or portion of SEQ ID NO:1, or “an HA1 protein from which HA2 is absent.” Further, Lai et al. teaches that the sequences are from equine-2 influenza virus, and ultimately for use in vaccines. Lai et al. also teaches that L39914 is

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from strain A/Equ/Kentucky/94. Lai et al. also teaches AF197241, which is 100% homologous to SEQ ID NO:1 (see result 1 of .rge), which is from strain A/Equ/Kentucky/98.

One of ordinary skill in the art would have been motivated to substitute the HA gene sequence from A/Equ/Kentucky/81 as taught by Olsen et al. with the fragments as taught by Lai et al. because the fragments represent current isolates more indicative of currently circulating equine influenza viruses and thus more likely to be encountered.

One of ordinary skill in the art would have had a reasonable expectation of success for substituting the sequences because one would have expected DNA vaccine against equine influenza vaccines to protect against currently circulating equine influenza strains.

Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

The 103(a) rejections over the various secondary references are maintained. The rejections are further recited for clarification purposes and to be considered in light of the elaborated positions in the first Office Action on the merits.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al. and Lai et al. in view of Chen et al.

See the teachings of Olsen et al. and Lai et al. above.

Olsen et al. and Lai et al. do not teach the vaccine composition further comprising recited additional antigenic components.

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Chen et al. teaches that a mixture of viral protein-expressing plasmid DNAs helps provide protection against heterologous viral infection.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the composition of Olsen et al. and Lai et al. and the components of Chen et al. because Chen et al. teaches such vaccines confer additional protection against homologous challenge and also help protect against heterologous challenge.

One of ordinary skill in the art at time would have expected broader protection by adding additional antigen encoding sequences because such additional sequences would be expected to stimulate immunity against additional antigenic features of the influenza virus.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al. and Lai et al. in view of Invitrogen.

See the teachings of Olsen et al. and Lai et al. above.

Olsen et al. and Lai et al. do not teach pcDNA3.1/V5-His-TOPO.

Invitrogen teaches the vector is a strong CMV promoter for high level expression.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the composition of Olsen et al. and Lai et al. and the vector of Invitrogen because Invitrogen teaches high level expression with said vector.

One of ordinary skill in the art at time the invention was made would have had a



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reasonable expectation of success for using the composition of Olsen et al. and Lai et al. and the vector of Invitrogen because these techniques were all well-characterized at the time of Applicant's invention as evidenced by the combined teachings of Olsen and Invitrogen.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 9, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al. and Lai et al. in view of Larsen et al.

See the teachings of Olsen et al. and Lai et al. above.

Olsen et al. and Lai et al. do not teach the peptide adjuvant.

Larsen et al. teaches the coadministration of plasmid DNA encoding cytokine/adjuvant IL-6 with plasmids encoding HA from equine-2 influenza strain A/Equine/Kentucky/1/81 (see page 1705).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the composition of Olsen et al. and Lai et al. and the peptide adjuvant of Larsen et al. because Larsen et al. teaches that coadministration conferred a significant adjuvant effect.

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for using the composition of Olsen et al. and Lai et al. and the peptide adjuvant of Larsen et al. because Olsen et al. and Lai et al. and Larsen et al. all teach equine influenza vaccine.

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Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al. and Lai et al. in view of Lunn et al.

See the teachings of Olsen et al. and Lai et al. above.

Olsen et al. and Lai et al. do not teach administration to equid.

Lunn et al. teaches nucleic acids for equine influenza virus and methods via administration to equid (See page 2247).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the equine vaccine composition of Olsen et al. and Lai et al. and the method of Lunn et al. because Lunn et al. teaches nucleic acid administration to equid.

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for using the composition of Olsen et al. and Lai et al. and the method of Lunn et al. because Olsen et al., Lai et al. and Lunn et al. all teach nucleic acid vaccines for equid.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

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Claims 12, 14, 15, 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al. and Lai et al. in view of Lunn et al. and Wong et al.

See the teachings of Olsen et al. and Lai et al. above in view of Lunn et al.

Olsen et al. and Lai et al. above in view of Lunn et al. do not teach liposome encapsulation.

Wong et al. teaches intranasal influenza HA vaccine delivery with and without liposome encapsulation, wherein it would have been obvious to optimize concentrations and liposome encapsulation demonstrated superior results.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the composition of Olsen et al. and Lai et al. in view of Lunn et al. and the liposome encapsulation of Wong et al. because Wong et al. teaches such a strategy induces mucosal immunity at the site of infection.

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for using the composition of Olsen et al. and Lai et al. in view of Lunn et al. liposome encapsulation of Wong et al. because the techniques were well-developed and provided in the combined teachings of Olsen et al., Lai et al., Lunn et al. and Wong et al.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

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Claim 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al. and Lai et al. in view of Lunn et al. and Wong et al. in further view of Invitrogen.

See the teachings of Olsen et al. and Lai et al. above in view of Lunn et al. and Wong et al.

Olsen et al. and Lai et al. above in view of Lunn et al. and Wong et al. do not teach pcDNA3.1/V5-His-TOPO.

See the teachings of Invitrogen above.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the composition and method of Olsen et al. and Lai et al. in view of Lunn et al. and Wong et al. and the vector of Invitrogen because Invitrogen teaches high level expression with said vector.

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for using the composition and method of Olsen et al. and Lai et al. in view of Lunn et al. and Wong et al. and the vector of Invitrogen because these techniques were all well-characterized at the time of Applicant's invention as evidenced by the combined teachings of Olsen and Invitrogen.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.


### ***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
M. Franco Salvoza  
Patent Examiner



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